Medicines Management Programme (MMP)

Roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting

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MEDICINES MANAGEMENT PROGRAMME

25 October 2018

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

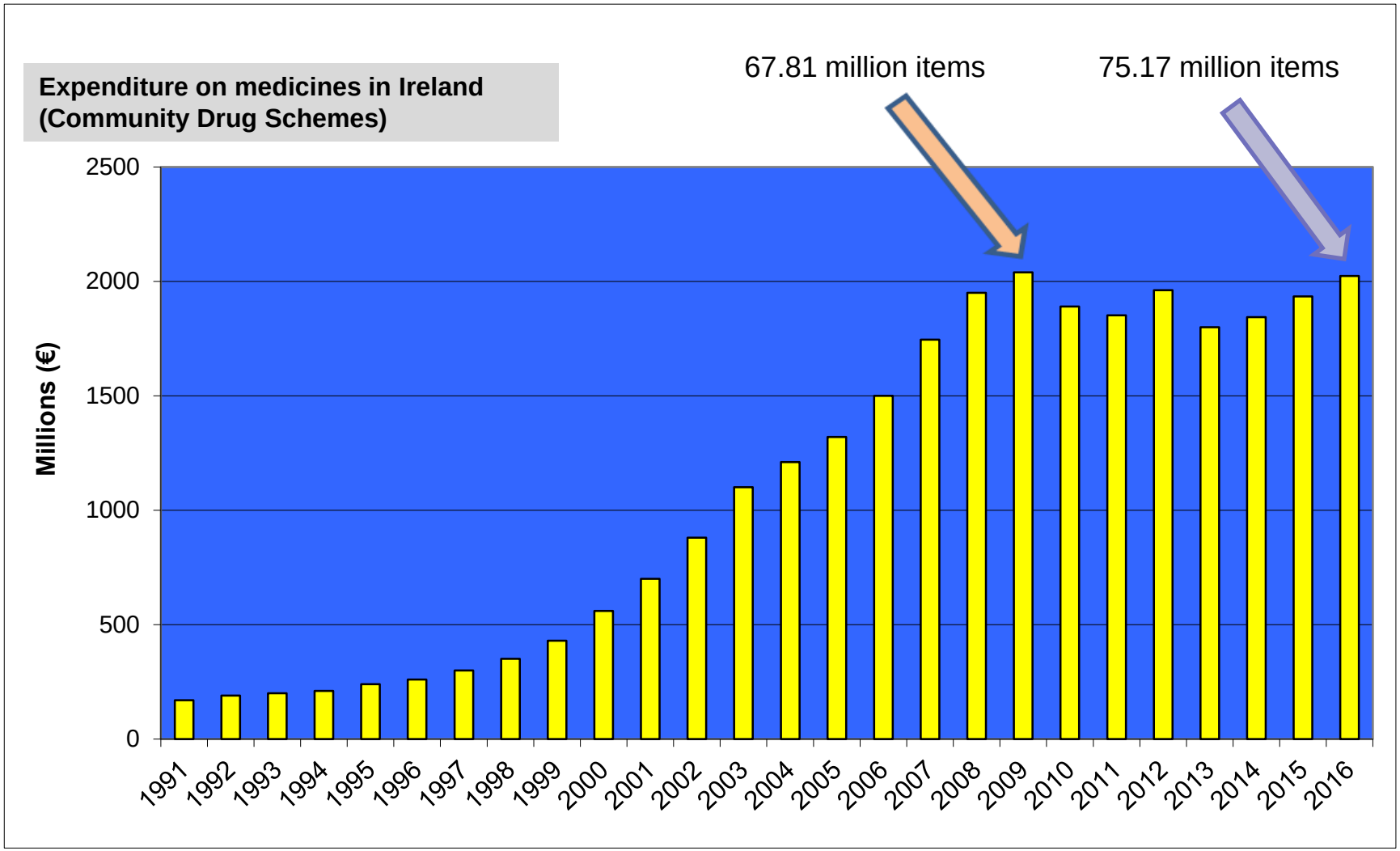
The HSE Medicines Management Programme (MMP) was established in January 2013

Aim:

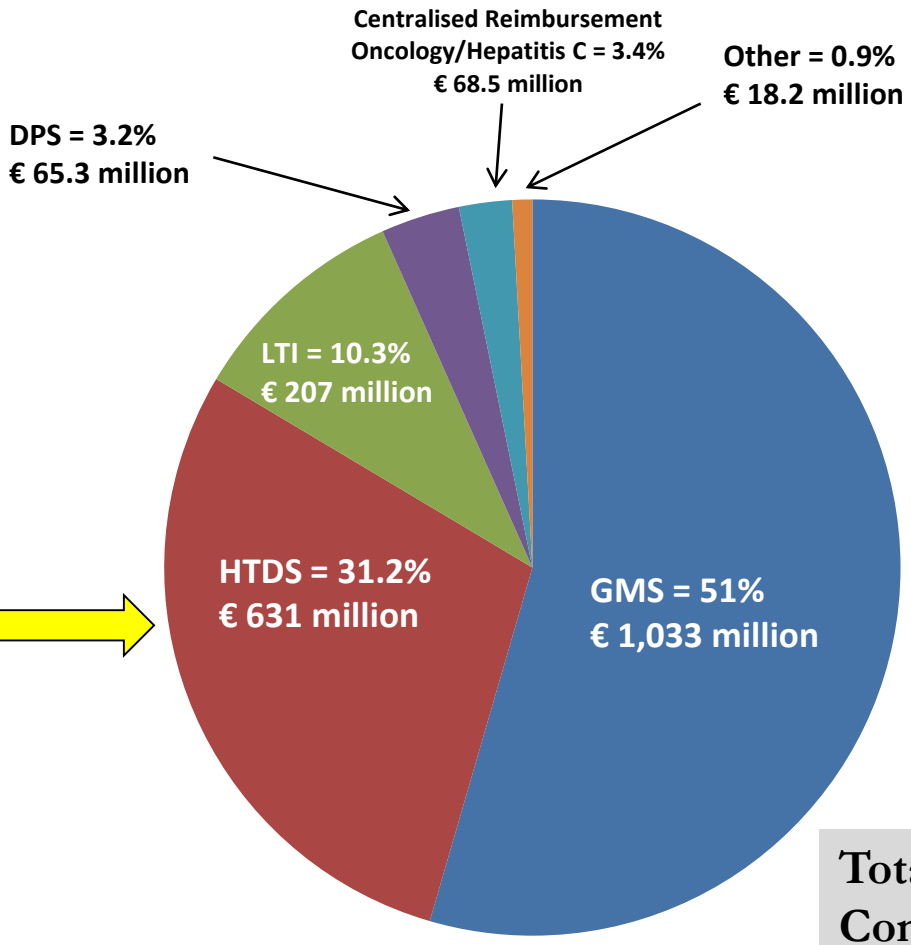
Sustained national leadership relating to:

- ✓ Safe
- ✓ Effective
- ✓ Cost-effective use of medicines

Total expenditure on medicines over €2.0 billion in 2016



Drug Expenditure in Ireland 2016



Items dispensed:
GMS 78%
DPS 10%
LTI 10%
HTDS 0.9%

Total expenditure under the Community Drugs Schemes:
€ 2,023 million

Areas of interest to the HSE-MMP

- Generic prescribing (safety & cost effectiveness)
- Preferred Drugs Initiative
- Inhaled medications
- DOACs
- Lidocaine 5% patch (Versatis®)
- Oral nutritional supplements
- Sacubitril/Valsartan (Entresto®)
- Biological medicines including biosimilars

Most expensive medicines

- Adalimumab [HTD]
- Clinical nutritional products
- Etanercept [HTD]
- Ivacaftor [HTD]
- Pregabalin
- Salmeterol + other drugs for OAD
- Lidocaine 5% medicated plaster
- Fingolimod [HTD]
- Lenalidomide [HTD]
- Formoterol + other drugs for OAD

HTD: High Tech Drug

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HTD: High Tech Drug

Biosimilar Medicines in the Irish Healthcare setting

Introduction

Biological medicines (or 'biologics') are treatments where the active ingredients are proteins such as hormones (erythropoietins, insulins and growth hormones), enzymes that are naturally produced in the human body, or monoclonal antibodies. They may also be blood products, immunological medicinal products and advanced technology products such as gene and cell therapies.[1] As biologic agents are complex molecules the production process is significantly more complicated than that for chemically synthesised medications.

A biosimilar medicine (or 'biosimilar') is a biological medicine that is developed to be highly similar to an existing biological medicine in physicochemical and biological terms. [2] Due to the complex manufacturing process biosimilars are not identical versions of the reference product so they are not considered to be generics. Therefore the issue of interchangeability and equivalence has become an area of intense review both in Europe and worldwide. The Health Products Regulatory Authority (HPRA) and the National Medicines Information Centre (NMIC) have recently produced comprehensive guides to biosimilar medicines, outlining the background, authorisation requirements and the role for biosimilar medicines in clinical practice, including guidance for practitioners.[3,4]

Background to Biosimilars

The European Union was the first region worldwide to have a legal framework and regulatory pathway for biosimilars and the first biosimilar was approved in 2006.[5] The European Medicines Agency (EMA) originally issued guidance in 2005 explaining that the approach to biosimilars would be different to generic products due to the complexity of the manufacturing process for biologics and this advice has been updated as recently as July 2015.[6,7] Following centralised approval of biosimilars by the EMA each country can then adopt their own approaches to pricing, reimbursement and substitution of biosimilars. Depending on the country these issues may be dealt with by legislation or by way of guidelines.[8] In Ireland the issue of substitution and interchangeability of biosimilars is addressed in legislation through the Health (Pricing and Supply of Medical Goods) Act 2013 which currently prohibits substitution of biological medicines.[9] Nearly two thirds of countries across Europe have either laws or guidelines in place to prohibit the substitution of biologics. [8]

The biosimilar approval process through the EMA is based on a robust comparability exercise which looks at three specific steps: quality comparability (physicochemical and biological), pre-clinical comparability (in vitro and in vivo studies) and clinical comparability (pharmacokinetics, pharmacodynamics, safety and efficacy).[3,4] This process is discussed in detail in recent publications by the HPRA and the NMIC.[3,4] The HPRA notes that quality comparability testing is seen as the cornerstone of biosimilarity and has been in place for many years when authorised biologics undergo changes to the manufacturing process which is common in this scientific area.[4]

Comparability of biological and biosimilar medicines

January 2016

NCCP Guidance on the use of Biosimilar Medicines in Cancer Treatment

Version	Date published	Amendment	Approved By
1	August 2017		Working Group
2	September 2017	Inclusion of link to HPRA information for patients	Working Group

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Biosimilars on the Community Drug Schemes

Biosimilars on the Community Drug Schemes

- Retacrit® Erythropoietin
- Accofil®
- Grastofil®
- Nivestim®
- Ratiogastrim®
- Tevagrastim®
- Zarzio®

Filgastrim

- Bemfola® Follitropin-α
- Omnitrope® Somatropin
- Abasaglar® Insulin glargine
- Benepali® Etanercept

Biological medicines on the Community Drug Schemes -2016

Biological medicine	Prescribing frequency	Expenditure*
Etanercept	63,356	€66.4 million
Somatropin	14,391	€8.4 million
Follitropin-α	8,740	€8.2 million
Erythropoietin	9,931	€4.6 million
Filgastrim	5,377	€3.0 million
Insulin glargine	115,038	€9.3 million

*Expenditure includes ingredient cost and VAT where applicable

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Adalimumab	93,067	€123.5 million

*Expenditure includes ingredient cost and VAT where applicable

Utilisation of Biosimilars - 2017

Biological medicine	Prescribing frequency	Expenditure*
Enbrel®	52,815	€54.8 million
Benepali®	267	€0.2 million

*Expenditure includes ingredient cost and VAT where applicable

MMP – BVB Medicines

1. Identify best-value biological (BVB) medicines in various therapeutic areas

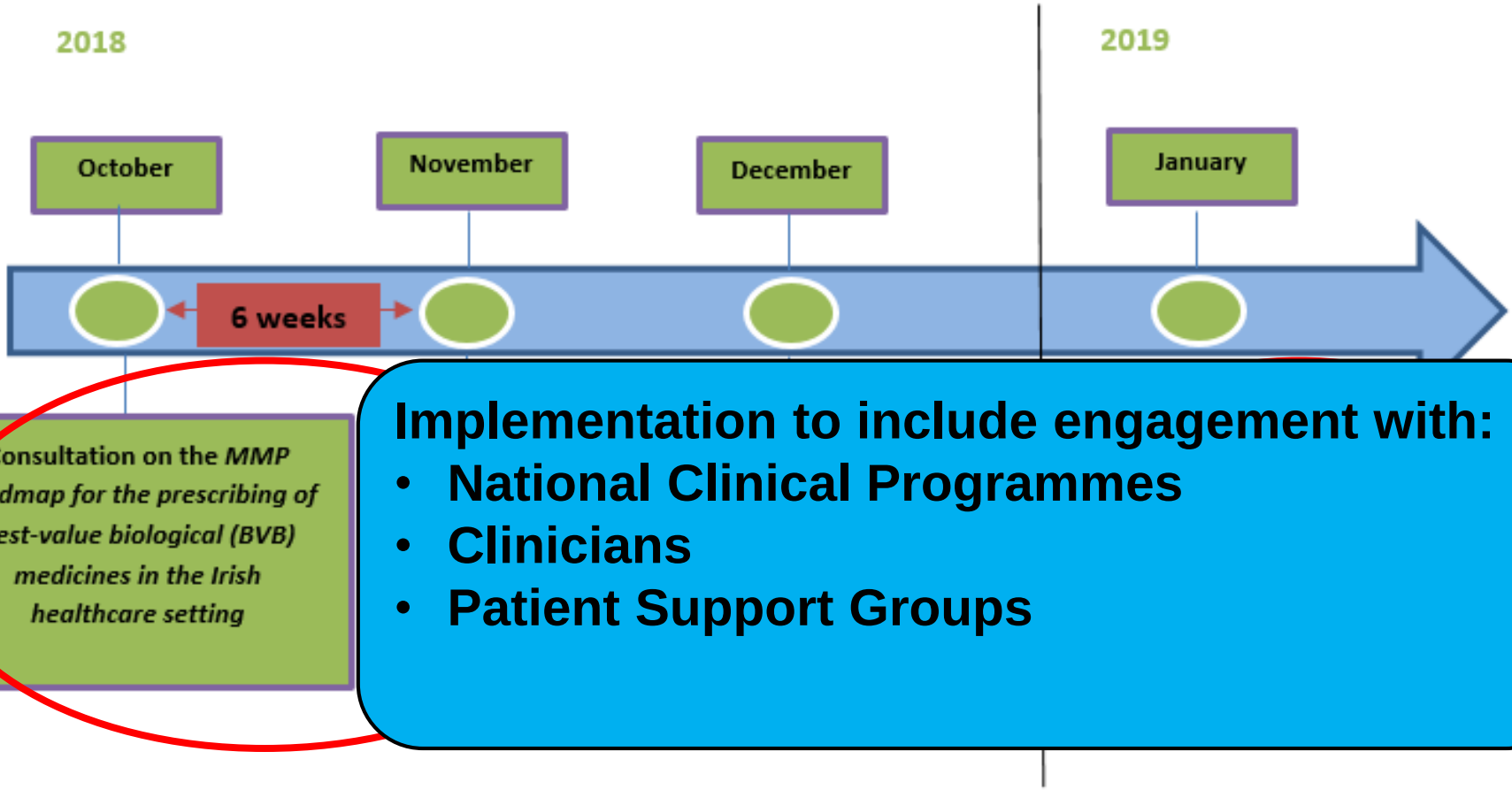
2. Publish Prescribing and Cost Guidance

3. Engage with stakeholders to support implementation of BVB medicines

Criteria for BVB Medicines

- Reimbursement price
- Therapeutic indications
- Formulation considerations
- Product range
- Product stability
- Administration devices
- Patient factors
- Current expenditure and potential for savings
- DoH National Biosimilar Policy
- Utilisation and clinical experience
- National clinical guidelines
- Robustness of supply
- Any other relevant factors

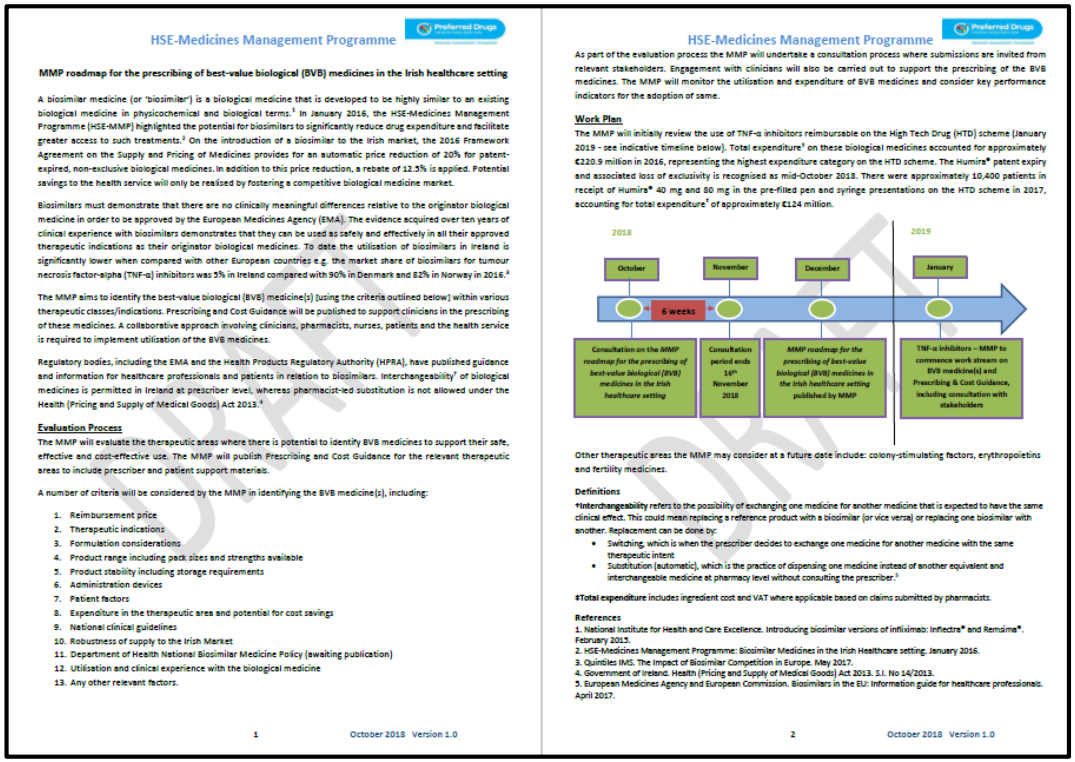
MMP – BVB Medicines



Implementation to include engagement with:

- **National Clinical Programmes**
- **Clinicians**
- **Patient Support Groups**

MMP – BVB Medicines Consultation



HSE-Medicines Management Programme

MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting

A biosimilar medicine (or 'biosimilar') is a biological medicine that is developed to be highly similar to an existing biological medicine in physicochemical and biological terms.[1] In January 2016, the HSE-Medicines Management Programme (HSE-MMP) highlighted the potential for biosimilars to significantly reduce drug expenditure and facilitate greater access to such treatments.[2] On the introduction of a biosimilar to the Irish market, the 2016 Framework Agreement on the Supply and Pricing of Medicines provides for an automatic price reduction of 20% for patent-expired, non-exclusive biological medicines. In addition to this price reduction, a rebate of 12.5% is applied. Potential savings to the health service will only be realised by fostering a competitive biological medicine market.

Biosimilars must demonstrate that there are no clinically meaningful differences relative to the originator biological medicine in order to be approved by the European Medicines Agency (EMA). The evidence acquired over ten years of clinical experience with biosimilars demonstrates that they can be used as safely and effectively in all their approved therapeutic indications as their originator biological medicines. To date the utilisation of biosimilars in Ireland is significantly lower when compared with other European countries e.g. the market share of biosimilars for tumour necrosis factor-alpha (TNF-α) inhibitors was 5% in Ireland compared with 90% in Denmark and 82% in Norway in 2016.[3]

The MMP aims to identify the best-value biological (BVB) medicine(s) (using the criteria outlined below) within various therapeutic classes/indications. Prescribing and Cost Guidance will be published to support clinicians in the prescribing of these medicines. A collaborative approach involving clinicians, pharmacists, nurses, patients and the health service is required to implement utilisation of the BVB medicines.

Regulatory bodies, including the EMA and the Health Products Regulatory Authority (HPRA), have published guidance and information for healthcare professionals and patients in relation to biosimilars. Interchangeability* of biological medicines is permitted in Ireland at prescriber level, whereas pharmacist-led substitution is not allowed under the Health (Pricing and Supply of Medical Goods) Act 2013.[4]

Evaluation Process

The MMP will evaluate the therapeutic areas where there is potential to identify BVB medicines to support their safe, effective and cost-effective use. The MMP will publish Prescribing and Cost Guidance for the relevant therapeutic areas to include prescriber and patient support materials.

A number of criteria will be considered by the MMP in identifying the BVB medicine(s), including:

1. Reimbursement price
2. Therapeutic indications
3. Formulation considerations
4. Product range including pack sizes and strengths available
5. Product stability including storage requirements
6. Administration devices
7. Patient factors
8. Expenditure in the therapeutic area and potential for cost savings
9. National clinical guidelines
10. Robustness of supply to the Irish Market
11. Department of Health National Biosimilar Medicine Policy (awaiting publication)
12. Utilisation and clinical experience with the biological medicine
13. Any other relevant factors.

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HSE-Medicines Management Programme

As part of the evaluation process the MMP will undertake a consultation process where submissions are invited from relevant stakeholders. Engagement with clinicians will also be carried out to support the prescribing of the BVB medicines. The MMP will monitor the utilisation and expenditure of BVB medicines and consider key performance indicators for the adoption of same.

Work Plan

The MMP will initially review the use of TNF-α inhibitors reimbursable on the High Tech Drug (HTD) scheme (January 2019 - see indicative timeline below). Total expenditure# on these biological medicines accounted for approximately €220.9 million in 2016, representing the highest expenditure category on the HTD scheme. The Humira® patent expiry and associated loss of exclusivity is recognised as mid-October 2018. There were approximately 10,400 patients in receipt of Humira® 40 mg and 80 mg in the pre-filled pen and syringe presentations on the HTD scheme in 2017, accounting for total expenditure# of approximately €124 million.

Other therapeutic areas the MMP may consider at a future date include: colony-stimulating factors, erythropoietins and fertility medicines.

Definitions

*Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference product with a biosimilar (or vice versa) or replacing one biosimilar with another. Replacement can be done by:

- Switching, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent
- Substitution (automatic), which is the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the prescriber.[5]

#Total expenditure includes ingredient cost and VAT where applicable based on claims submitted by pharmacists.

References

1. National Institute for Health and Care Excellence. Introducing biosimilar versions of infliximab: Inflectra® and Remsima®. February 2015.
2. HSE-Medicines Management Programme: Biosimilar Medicines in the Irish Healthcare setting. January 2016.
3. Quintiles IMS. The Impact of Biosimilar Competition in Europe. May 2017.
4. Government of Ireland. Health (Pricing and Supply of Medical Goods) Act 2013. S.I. No 14/2013.
5. European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. April 2017.

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Email submissions to mmp@hse.ie by Friday 16th November 2018
Available at www.hse.ie/yourmedicines - *Consultation* section

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Consultation

Best-value biological medicines

The Medicines Management Programme (MMP) is now undertaking a period of consultation in relation to MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting.

Submissions in relation to this draft roadmap are invited from relevant stakeholders including clinicians, professional bodies and the pharmaceutical industry. We regret that the MMP cannot accept submissions from members of the public.

The closing date for submissions is 5pm Friday 16 November 2018. Submissions should be emailed to mmp@hse.ie.